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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,504	08/18/2000	J. Bruce Pitner	P-2776P1P1P1	7467

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/642,504	PITNER ET AL.	
	Examin r	Art Unit	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-16,49-62,91,93-97 and 99-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-16,49-62,91,93-97 and 99-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The RCE Request and amendment received 10/6/03 have been entered and claims 1-12, 14-16, 49-62, 91, 93-97, 99-102 are currently pending in this application. The amended title is acceptable. Please update the preamble of the specification regarding related applications.

In view of the amendments to the claims and arguments presented, the rejections of record under 35 USC 112, first and second paragraphs, are hereby withdrawn.

In view of the comments regarding related applications, no priority is granted, the filing date of this application is 8/18/2000.

A reading of the claims and specification do not reveal a specific functional problem solution or any particular point of novelty. Therefore, what has been searched and considered here, is immobilizing the conventional luminescent indicator. No weight is given to repeating measurements in an assay nor to some control in an assay. Both are old and the present specification reveals no surprising results of same.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 14-16, 49-62, 91, 93-97, 99-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Bacon and Parker.

Bacon (Anal Chem) entitled "Determination of Oxygen Concentrations by Luminescence Quenching of a Polymer Immobilized Transition Metal Complex" teaches in the abstract, tris(4,7-diphenyl-1, 10-phenanthroline)ruthenium(II) immobilized in a silicone rubber for measuring oxygen concentrations. On page 2780 column 2, silica

gel bound luminescent dye is separated from the solution being measured. On page 2781 column 2, a number of polymers were tried and their qualities discussed.

Parker (Fiber Optic Sensors) entitled "Chemical Sensors Based on Oxygen Detection by Optical Methods" teaches in the abstract, fluorescence quenching to measure oxygen concentration with 9,10-diphenyl anthracene. On page 156, even when immobilized, fluorescent molecules show a reduction in fluorescence intensity with increasing oxygen concentration. Thus, solid materials can be developed to measure the concentration of oxygen. Chemical reactions that either consume or produce oxygen can be determined. The fluorescence compound may be physically immobilized in a polymer such as silicone. On page 157 the reactions take place in cuvettes.

The independent claims differ from the above references in that they recite the enzyme is in solution.

Claims 5 and 53 differ from the above references in that they specify the compound is adsorbed on solid silica particles. Claims 8, 9, 56, 57 differ from the above references in that they are directed to other ruthenium salts. Claims 11 and 12 differ from the above references in that they are directed to the solutions are open or closed. Claims 14-16, 60-62 differ from the above references in that they are directed to the enzymes are in specific cells and may include P450 enzymes particularly. New claims 91, 93-97, 99-102 are directed to materials for promoting cell growth.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the enzyme in solution because the references teach solutions contact the enzyme and the enzymes may be combined with other components. The examiner interprets "in solution" broadly where the enzyme may be combined with a matrix or contact other solutions. The solutions of the references are either open or closed and both are shown in the references cited herein for measuring oxygen concentrations. Further, to immobilize the luminescent compound on silica particles because silica particles are well known in this art for immobilizing desired compounds. The references teach common ruthenium compounds and the presently claimed compounds are known in this art for their claimed function. No novelty is seen in the analyte being any particular type of cell or known redox enzyme system where the method of measuring is known for the same function as claimed and would have the expected results. The addition of materials to promote cell growth in assays for cell related processes is old in this art. See the many references cited of interest. The claims are unclear as to what may or may not be immobilized or in solution nor what the function of such may be. It is well known to immobilize or solubilize desired components.

No novelty is seen in employing repeated measurements as needed because no need is shown and no degree of precision is required.

Applicant's arguments filed 10/6/03 have been fully considered but they are not persuasive.

Applicants argue that Bacon does not teach the determining in solution or comparing the experimental to controls and repeating the measurement as needed. Claim 49 recites the sensor is not in contact with the solution which is not taught by Bacon. Further, Bacon is directed to interferents of quenching where the barrier film separates substances that would damage the sensor dye. The success of the sensor of Bacon depends on the polymer in which the sensor is contained serving as an effective barrier to potential interferents. Bacon does not suggest that a sensor in contact with a sample would be impermeable to the materials in the sample, including the enzymes. Regarding Parker, the present claims require at least one enzyme in a solution where Parker has the enzyme immobilized with the dye. Also Parker does not teach a control and repeating measurements.

It is the examiner's position that the present claims require the determination of an enzyme in a solution with a sensor which sensor is contained within a matrix. Bacon and Parker clearly teach determining oxygen in enzyme solutions. The dye to detect the solutions contacts the solutions. See for example in the abstract of Parker detecting glucose with glucose oxidase. The present claims immobilize the sensor as does both references.

Much of applicants' arguments are centered upon unclaimed limitations, such as the function of the barrier film, interferents as related to the barrier film, and an enzyme in solution which is encompassed by an enzyme being in a solution of the polymer. It is respectfully submitted that in order for evidence of unexpected results to be sufficient to

rebut a prima facie case of obviousness, the evidence must be commensurate in scope with the claims.

Regarding controls, the data obtained from both references is in some inherent manner calibrated and the standard method of calibration is with controls. Controls are well known in the determining arts and no novelty is seen in employing controls for any known function with the expected result. See page 162 of Parker who shows graphs to calibrate the determinations. Bacon also discusses calibrations.

Regarding repeating measurements, the graphs of Parker show repeated measurements. Further, the present claims repeat the measurements as needed so if Parker and Bacon did not need to repeat the measurements, their methods would read on the present claims. No function or criteria are claimed for any repetition of any measurements to any degree of precision.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Ralph Gitomer
Primary Examiner
Art Unit 1651

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